FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

Dated: November 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21971 Filed 11–8–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0430]

Agency Emergency Processing Under Office of Management and Budget Review; Orphan Drug Products; Common European Medicines Evaluation Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is an amendment to OMB control number 0910–0167 and concerns the joint adoption by FDA and the European Medicines Evaluation Agency (EMEA) of the Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (form FDA 3671).

DATES: Fax written comments on the collection of information by November 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number ''0910–0167'' and the title, ''Orphan Drug Products; Common EMEA/FDA Application Form for Orphan Medicinal Product Designation.'' Also include the FDA docket number found in brackets in the heading of this document. To obtain a copy of the draft form FDA 3671, please call Mary Grice at 301–827–3666 or submit written requests via fax to 301–827–0017.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13) to enable the agency to jointly announce with EMEA the adoption of the Common EMEA/FDA Application Form for Orphan Medicinal Product Designation at the European Union (EU)-wide Administrative Simplification Workshop on November 28, 2007. The information is essential to the agency's mission of protecting and promoting the public health. The use of the normal clearance procedures would likely result in the prevention or disruption of this collection of information.

With respect to the collection of information, FDA invites comments on these topics: (1) The clarity and ease of use of this proposed common application form; (2) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (3) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility, and clarity of the information to be collected; and (5) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology.

Orphan Drug Products; Common EMEA/FDA Application Form for Orphan Medicinal Product Designation—(OMB Congrol Number 0910–0167)—Amendment

This common application form is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States and EU mandated by the Transatlantic Economic Council (TEC). The TEC mandate involves: Removal of barriers to transatlantic commerce; rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector; achieving more effective, systematic, and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers; removing unnecessary differences between jurisdictional regulations in order to foster economic integration; reinforcing the existing transatlantic dialogue structures in regulatory cooperation, both by intensifying our sector-by-sector United States-EU regulatory cooperation and our dialogue between OMB and the European Commission services on methodological issues.

At present, when seeking orphan designation of the same drug for the diagnosis, treatment, or prevention of the same rare disease or condition in the United States and in the European Community, a sponsor must submit a designation request to FDA (in accordance with section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)) and a separate designation application to EMEA (in accordance with Regulation (EC) No. 141/2000 of December 16, 1999, and Commission Regulation (EC) No. 847/2000). In most cases, the two documents are formatted differently to meet regulatory demands, but the required core information elements are similar with the exception of some unique regulatory requirements exclusive to each jurisdiction. Therefore, FDA and EMEA believe that a common application form will help reduce the sponsor's regulatory burden and costs to produce and submit a differently-formatted request/application. In addition, a common application form may also streamline the administrative and substantive regulatory review processes, and aid in information exchange between the agencies. In accordance with the Confidentiality Arrangements concluded on September 12, 2003, between the European Commission, EMEA, and FDA,[1] FDA and EMEA have agreed in principle to adopt a template for the common application form as proposed in form FDA 3671.

Any sponsor seeking orphan designation of the same drug for the same disease or condition from both FDA and EMEA may use this common application form for regulatory filing purposes. A sponsor may also use this common application form when seeking designation only from FDA. This

[1]See ''Confidentiality Arrangements Concluded Between the EU (EC and EMEA) and the US FDA/DHHS Implementation Plan for Medicinal Products for Human Use'' at *http://www.fda.gov/oia/arrangements0904.html*.

common application form is intended to complement, not to supersede, the relevant regulatory frameworks currently in effect. The sponsor must comply with all applicable regulatory requirements in each jurisdiction in which it seeks designation when using this common application form.

To use the common application form, the sponsor must provide the required information in each applicable section as instructed in the explanatory notes. Certain information elements are identified in the form as required exclusively by either FDA or EMEA regulations, and as such they must be included only in the application to that jurisdiction. Where additional explanations and/or supportive documents are necessary, the sponsor should sequentially append them at the end of the common application form in the order they appear in the form. The sponsor must also complete the declaration and signature page. For FDA, the completed common application form and required appended documents must be submitted to the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. For EMEA, the completed documents must be submitted to European Medicines Agency, 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom.

FDA estimates the reporting burden of this common application form as follows. Between January 2000 and May 2006, FDA and EMEA received 226 comparable orphan designation requests/applications of the same drugs for the same diseases or conditions, or an average of 35 per year. With the ease of a common application form, FDA anticipates the number of such requests/applications may increase over time. Therefore, generally there is one request/application per respondent and as, at the extreme, all respondent are U.S.-based, FDA believes up to 40 such respondents may use the common application form each year. The respondents will be primarily pharmaceutical companies or other for-profit organizations. The collection of information for sponsors requesting orphan drug designation from FDA is currently covered by the Orphan Drug Regulations (21 CFR Part 316) and approved under OMB No. 0910–0167 (expires August 31, 2010). For applications submitted exclusively to FDA, we do not believe the new form will result in any increased burden on the respondents and therefore we estimate no additional burden for those respondents. FDA believes the information required for the EMEA submission, for the most part, is very similar to that in the FDA submission, which is already in the respondents' possession. The respondents, however, may have to search existing data sources or gather additional needed data, such as on the prevalence or the availability of alternative methods of diagnosis, prevention, and treatment of the rare disease or condition of interest in the European Community, to complete the EMEA submission. FDA estimates that it will take an additional 32 hours (16 hours of professional time and 16 hours of support time) to compile information required for the EMEA submission. Hence, the estimated total annual human resource hours, at most, would be 1,280 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	Annual No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3671	40	1	40	32	1,280

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21988 Filed 11–8–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007M–0366]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability through the Internet and FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

FOR FURTHER INFORMATION CONTACT: Pamela Pope, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at *http://www.fda.gov*. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act.